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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1653

DATE MAILED: 08/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

84-55

Office Action Summary

Application No.

10/048,193

Applicant(s)

LEE ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4 and 6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4 and 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 May 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1, 2, 4 and 6 are pending.

Applicants' amendment filed May 20, 2004 is acknowledged. Applicants' response has been fully considered. Claims 1, 4 and 6 have been amended, and claims 3 and 5 have been cancelled. Thus, claims 1, 2, 4 and 6 are examined.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

2. The previous rejection of claims 1-6 under 35 U.S.C. 112, second paragraph, regarding the cited terms is withdrawn in view of applicants' amendment to the claim, applicants' cancellation of the claim, and applicants' response at page 2 in the amendment filed May 20, 2004.

Claim Rejections - 35 USC § 102

3. The previous rejection of claim 3 under 35 U.S.C. 102(b) as anticipated by Salmon *et al.* (Protein Expression and Purification 9, 203-210 (1997)), is withdrawn in view of applicants' cancellation of the claim in the amendment filed May 20, 2004.
4. The previous rejection of claim 5 under 35 U.S.C. 102(b) as anticipated by Miehlike *et al.* (J. Clinical Microbiology, 34, 2593-2594 (1996)), is withdrawn in view of applicants' cancellation of the claim in the amendment filed May 20, 2004.
5. The previous rejection of claims 5 and 6 under 35 U.S.C. 102(b) as anticipated by Arnold *et al.* (Infection and Immunity 28, 893-898 (1980)), is withdrawn in view of applicants' cancellation of the claim, applicants' amendment of the claim, and applicants' response at page 2 in the amendment filed May 20, 2004.

Objection to New Matter Added to Specification

6. The amendment filed May 20, 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The original Fig. 2 does not indicate human lactoferrin gene is inserted into a specific "pT3T3 18U vector" to form recombinant plasmid ph Lf-8 and/or the partial nucleotide sequence of pBacPAK8, while the newly submitted Fig. 2, and the amended claims 1 and 4 recite the new matters.

Applicant is required to cancel the new matter in the reply to this Office Action.

Informalities

The disclosure is objected to because of the following informalities:

7. Fig. 2 contains letters, which are too small to read. Appropriate correction is required. Fig. 2 also contains nucleotide sequence, however, there is no sequence listing provided. Applicants must comply with the requirements of the sequence rules, 37 CFR 1.821-1.825 and provide a copy of sequence listing and a computer readable form (CRF) containing all the sequences.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, 2, 4 and 6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 2, 4 and 6 are directed to a method for producing human lactoferrin using an insect cell, a recombinant insect virus, and a biological verification method for a recombinant lactoferrin. The specification only indicates human lactoferrin is produced by a method using an insect cell comprising the step of combining a transfer vector with a recombinant plasmid pHLf-8 to prepare a recombinant expression vector pBacLf which is modified having a polyhedrin promoter to regulate lactoferrin gene (page 5, line 18-page 6, line 9; original Fig. 2), however, it does not disclose the recombinant plasmid pHLf-8 is pT7T3-hLf and is constructed by inserting human lactoferrin gene into pT7T3 18U backbone and the partial nucleotide sequence of pBacPAK8 as indicated in the newly submitted Fig. 2 and the amended claims 1 and 4. Furthermore, there is no indication in the original specification that pT7T3 18U backbone has been used. The lack of description of construction of recombinant plasmid pHLf-8 using pT7T3 18U backbone, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1, 2, 4 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, 4 and 6 are indefinite because of the use of the term “resulting from homologous recombination through AcMNPV and AcNPV site”. The term “resulting from homologous recombination through AcMNPV and AcNPV site” renders the claim indefinite, it is not clear what the term “through AcMNPV and AcNPV site” means, does it mean homologous recombination occurs at the virus of AcMNPV and AcNPV, or does it mean homologous recombination occurs at a site in AcMNPV and AcNPV. Claims 1, 2 and 6 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

10. Claim 6 is indefinite as to “A biological verification method for a recombinant human lactoferrin”, it is not clear how the recombinant lactoferrin is verified as a human lactoferrin since the method only recites measuring the anti-bacterial activity of the protein, it does not contains the step of verifying the protein as recombinant human lactoferrin.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Naidu *et al.* (Antimicrobial Agents and Chemotherapy 240-245 (1993)) taken with Li *et al.* (U.S. Patent 5,861,238, January 19, 1999).

Naidu *et al.* disclose the determination of the antibacterial activity of bovine lactoferrin against *Salmonella typhimurium* and its mutants by measuring the conductance of the cultivation media of the bacteria in the presence of lactoferrin at different concentrations (page 241, right column, last paragraph; page 243, left column; Table 2). However, Naidu *et al.* do not disclose the use of human lactoferrin. Li *et al.* disclose both bovine and human lactoferrins contain an N-terminal AGE (advanced glycosylation endproducts) binding cysteine loop as a bactericidal domain. At the time of invention was made, it would have been obvious that one of ordinary skill in the art has been motivated to combine the two references to verify the anti-bacterial activity of human lactoferrin against *Salmonella typhimurium* in view of the AGE binding cysteine loop conserved across species because the method would provide the information indicating this AGE binding cysteine loop may be responsible for the bacterial binding

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properties of human and bovine lactoferrins and other defense proteins (column 16, lines 1-24). Thus, the combined references result in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

Conclusion

12. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner

CMK

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July 29, 2004

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